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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,695	07/08/2003	Hsu-Shan Huang	HUAH104	9695

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,695

Applicant(s)

HUANG, HSU-SHAN

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,10,11 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,10,11 and 13-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 4-9, 12 and 19-25 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.
3. The rejection of claims 1-3, 10, 11 and 13-18 under 35 USC 112, first paragraph is maintained.

Applicant argues (a) formula I is a general formula showing four different positions can be substituted but all of the inventor's compounds are bis-substituted and (b) in regards to claims 13-18, that detailed results were shown in applicant's publications (Exhibits A-H) and that it is impossible to predict the side effects and application in treatment of diseases utilizing the claimed compounds and thus, only the results of biological evaluation were shown. Applicant's argument was considered but not persuasive for the following reasons.

As stated by applicant, the claimed formula shows four different positions that can be substituted by the recited substituents and, thus, the claimed compounds encompass tetra-substituted compounds. Also as stated by applicant, all of applicant's compounds are bis-substituted and, thus, the present specification does not convey to

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the skilled artisan in the art that applicant had possession of the scope of compounds encompassed by the instant claims.

In response to applicant's argument as they relate to claims 13-18, it is noted that 35 USC 112 requires that the "specification", not applicant's publications, "shall contain a written description of the invention". Therefore, the exhibits are noted but not relevant.

Lastly, applicant argues it is impossible to predict the side effects and application in treatment of diseases utilizing the claimed compounds and, thus, only the results of biological evaluation were shown. It is unclear what is meant by this argument. If according to applicant, it is impossible to predict the utilization of the claimed compounds in "their application for diseases" then how can applicant suggest the present specification reasonably convey to the skilled artisan in the art that at the time of the present application, that applicant had possession of the claimed invention? The examiner maintains that the present specification lacks correlation between the effects disclosed by the present specification and treatment of a representative number of diseases encompassed by the instant claims.

For these reasons and those given in the previous Office Action, the rejection of claims 1-3, 10, 11 and 13-18 under 35 USC 112, first paragraph is maintained.

4. The rejection of claims 13-18 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicant argues that for the skilled artisan, the novel compounds **can** be candidate for antitumor drugs and **should** have potential cytotoxicity, antioxidant activity, telomerase activity etc. Applicant's argument was considered but not persuasive for the following reason.

The issue is not whether the compounds "**can**" be candidates for antitumor drugs and "**should**" have potential cytotoxicity, antioxidant activity, telomerase activity etc. 35 USC 112, requires that present specification "**shall**" contain a written description of the invention, and of the manner and process of making and using it, in such **full, clear, concise and exact terms as to enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and **shall set forth the best mode contemplated by the inventor of carrying out his invention**".

The present specification lacks a written description of the claimed invention in full, clear, concise and exact terms as required and, thus, it fails to enable the skilled artisan in the relevant art to make and use the claimed invention.

For these reasons and those given in previous Office Action, the rejection of claims 13-18 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is maintained.

5. The rejection of claims 4-9, 12 and 19-25 under 35 USC 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention is made moot by the cancellation of the instant claims.

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6. The rejection of claims 1-3, 10, 11 and 13-18 under 35 USC 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention is maintained.

Applicant argues that tetra-substituted anthraquinones are not disclosed.

Applicant's argument was considered but not persuasive for the following reason.

The examiner notes that tetra-substituted anthraquinones are not disclosed by the present specification. However, tetra-substituted anthraquinones are encompassed by the instant claims.

For this reason and those given in the previous Office Action, the rejection of claims 1-3, 10, 11 and 13-18 under 35 USC 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention is maintained.

7. The rejection of 4-9 under 35 USC 112, second paragraph, as being indefinite is made moot by the cancellation of the instant claims.

8. The rejection of claims 1-3 and 13-18 under USC 112, second paragraph, as being indefinite is maintained.

Applicant argues (a) the groups cited by the examiner define complete substituents and, thus, clear; (b) claim 1 recites groups for long chain and alkyl substitutions, whereas claim 2 recites groups for aromatic and heterocyclic substitutions and (c) "the biological evaluation mentioned for cytotoxicity, lipid peroxidation, telomerase activity and other assays can be predicted as these compounds have

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potential applications for these diseases". Applicant's argument was considered but not persuasive for the following reasons.

First, the recitation of groups such as "-S-, OCO- and -N- in the definition of Ra-Rg result in incomplete substituents. For example, if R1 is methyl substituted with one of the -S-, the substituent would be "-CH₂S-. Also, nitrogen has three bonds and, thus, "-N-" and "-N-Re" would also be incomplete.

Second, claims 2 and 3 are dependent on claim 1 and, thus, should limit claim 1. In other words, claims 2 and 3 cannot recite groups not encompassed by parent claim 1.

Lastly, the issue is not whether predictions can be made as to the potential applications for diseases but whether the claims identify diseases that are to be treated by the claimed compounds. The instant claims lack identification of diseases to be treated by administration of the claimed compounds and, thus, the metes and bound of the claimed invention is indefinite.

For these reasons and those given in the previous Office Action, the rejection of claims 1-3 and 13-18 under USC 112, second paragraph, as being indefinite is maintained.

Duplicate Claims

9. The objection to claims 4-9 and 19-25 under 37 CFR 1.75 as being substantial duplicates of claims 1 and 11, respectively, is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 102

10. The rejection of claims 4-9 and 19-25 under 35 USC 102(b) over Allen et al. (US 2,611,772) is made moot by the cancellation of the instant claims.

11. The rejection of claims 1 and 11 under 35 USC 102(b) over Allen et al. (US 2,611,772) is maintained.

Applicant argues the reference teaches 1,4,5,8-tetraamino-anthraquinones not shown by the instant claims. Applicant argument was considered but not persuasive for the following reason.

The instant claims recite compounds of formula I having R1-R4 that can be selected from several groups. With the substitution of R1-R4 with one of the recited substituents, the compound obtained would be tetra-substituted and, thus, the compounds taught by the cited reference are encompassed by the instant claims. The issue is not what applicant intends but what is encompassed by the instant claims.

For this reason and those given in the previous Office Action, the rejection of claims 1 and 11 under 35 USC 102(b) over Allen et al. (US 2,611,772) is maintained.

12. The rejection of claim 12 under 35 USC 102(b) over Patterson (US 5,132,327) is made moot by the cancellation of the instant claim.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

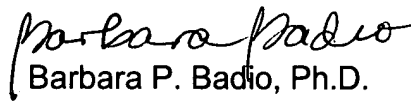
Telephone Inquiry

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
May 4, 2006